

UNITED STATES NUCLEAR REGULATORY COMMISSION

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November 13, 2020

MEMORANDUM TO: Blake D. Welling, Acting Director

Division of Nuclear Materials Safety

Region I

David L. Pelton, Director

Division of Nuclear Materials Safety

Region III

Mary C. Muessle, Director

Division of Nuclear Materials Safety

Region IV

FROM: Kevin Williams, Director

Division of Materials Safety, Security, State,

and Tribal Programs

Office of Nuclear Materials Safety

and Safeguards

SUBJECT: GUIDANCE FOR PERFORMING NRC RECIPROCITY

INSPECTIONS

On March 2, 2020, the latest revision to Inspection Manual Chapter (IMC) 2800, "Materials Inspection Program," was issued. This revision modified the inspection criteria and frequency for reciprocity inspections and provided guidance for taking a performance-based, risk-informed approach to conducting these inspections.

Previously, reciprocity inspections were performed in accordance with IMC 1220, "Processing of NRC Form 241, 'Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, and Offshore Waters,' and Inspection of Agreement State Licensees Operating under 10 CFR 150.20." IMC 1220 required 20 percent of Priority 1, 2, and 3 candidate licensees from the candidate pool to be inspected every year. The candidate pool was described in IMC 1220. During the last revision for IMC 2800, IMC 1220 was cancelled, and reciprocity inspection information was changed and placed in IMC 2800. The latest revision of IMC 2800 did not contain a specific metric for the number of reciprocity inspections that needed to be performed; rather, it focused on performing these inspections in a performance-based, risk-informed manner.

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IMC 2800 also noted that the U.S. Nuclear Regulatory Commission (NRC) regional offices could establish their own goals and methods for achieving the objectives for reciprocity inspections as described in Section 07.04, "Reciprocity Inspections," in IMC 2800.

This memorandum contains guidance previously reviewed and agreed to among the regional offices for meeting the goals and methods noted in Section 07.04 of IMC 2800. This guidance should be used in conjunction with the information provided in Section 07.04 of IMC 2800. Reciprocity guidance information in this memorandum will be added to the next revision of IMC 2800, as needed. In the interim if there are conflicts between this guidance and IMC 2800, the guidance in this memorandum takes precedence.

Effective December 1, 2020, regional offices shall use this guidance for determining the need for reciprocity inspections and the criteria to be used in making these determinations. Please direct any questions or comments to the point of contact for this document.

Enclosure:

Guidance for Conducting Reciprocity Inspections

SUBJECT: GUIDANCE FOR PERFORMING NRC RECIPROCITY INSPECTIONS

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GUIDANCE FOR CONDUCTING NRC RECIPROCITY INSPECTIONS

Reciprocity inspections are considered when entities licensed by an Agreement State perform work in an NRC jurisdiction (i.e., a non-Agreement State or an area of exclusive federal jurisdiction). When assessing the need for a reciprocity inspection, the following concepts should be considered in reaching a determination:

- Persons applying for reciprocity are licensed by another regulator. That regulator has reviewed the licensee's program for handling nuclear material and has found it to be acceptable.
- 2) Decisions concerning reciprocity inspections should be risk informed. Risk informed decision making includes a risk component and a deterministic component. The risk component is provided by applying the risk triplet (i.e., What can go wrong? How likely is it? What are the consequences?). The deterministic component is provided by the Agreement State licensing and inspection process. The Agreement State licensing process provides for a baseline review of a licensee's radiation program and the inspection process provides a review of its ability to execute that program. Because the NRC's determination as to whether to conduct a reciprocity inspection takes into account both the risk component and the deterministic component, this determination is risk-informed and not just risk-based (i.e., solely based on risk information). The Be RiskSMART framework provides an approach to considering these sorts of decisions (see https://usnrc.sharepoint.com/teams/Be-riskSMART).
- 3) Some activities are of sufficient risk or consequence to merit safety oversight, independent of the jurisdiction in which the activity occurs. These activities may merit reciprocity inspection as a means to provide appropriate safety oversight.
- 4) Past performance of a licensee, either enforcement or inspection, that is obtained from NRC or Agreement State sources may be useful in reaching a decision to conduct an inspection.
- 5) Announcing inspections is consistent with accomplishing the goals for conducting reciprocity inspections for high risk activities.

Reciprocity notifications are made using NRC Form 241. As part of licensing activities, the NRC regional office will evaluate each initial Form 241. To the maximum extent possible, given the information provided on the form, this evaluation will include a review of the activities to be performed. This evaluation may also include a review of inspection and enforcement history and a determination of whether other indicators for the consideration of reciprocity inspections, as listed in IMC 2800¹, exist. Initial results of the evaluation of the forms should be passed to the Region's inspection personnel for further consideration.

¹ Other criteria to consider for performing reciprocity inspections are:

[•] need for a reactive inspection based on on-going event;

[•] review of an allegation, as it relates to the work being conducted under reciprocity;

[•] inspection priority and scope of work to be performed;

[•] inspection, enforcement, and incident history (e.g., discussions with regulatory agency that issued license, NMED, National Enforcement Database, etc.);

duration (i.e., length of work/storage or number of visits in a calendar year);

knowledge of work in other regulatory jurisdictions (e.g., number of inspections of this entity in a given year under the National Materials Program);

new or unique technology; or, any other situation as deemed appropriate by the regional management.

When evaluating an activity for risk, high risk activities are those that have a higher probability of a failure in either equipment or procedure and a high consequence to public health and safety due to either exposure of personnel or contamination. Operations with a higher probability of failure can generally be considered to include nonroutine operations (e.g., repairs or modifications). Operations with a high consequence to public health and safety can generally be construed to include activities performed by Priority 1 and Priority 2 licensees that directly involve high activity sources. The most common activities meeting both these criteria include source exchange, as well as repair or modification of medical equipment containing large sources such as self-shielded irradiators or gamma stereotactic radiosurgery units. Since these are infrequently performed, high consequence evolutions, possibly conducted outside the licensee's originally licensed locations of use, high consideration should be given for conducting an inspection. To facilitate open and transparent communication and coordination with licensees, these inspections should typically be announced to provide certainty that the activity will be conducted while NRC inspectors are present. If, after reviewing the Form 241, the regional office decides not to conduct a reciprocity inspection for a high-risk activity, the rationale for this decision should be documented. Documentation should include an assessment of the risk of the activity (qualitative or quantitative), inspection resource challenges, licensee past performance, or other information supporting the decision to not conduct the inspection.

Decisions concerning whether to conduct a reciprocity inspection will also be needed for lower risk activities (i.e., not high-risk activities as defined above). These activities may include (but are not limited to) those of Priority 3 and lower priority licensees or those activities that do not directly affect sources of any size or directly affect sources of lower activity (e.g., in-field use of portable moisture density gauges, support for materials licensees' decommissioning activities). When making such decisions, the lower risk of these activities and ongoing Agreement State oversight provides a basis for not expending NRC resources to conduct a reciprocity inspection. However, in a few cases, there may be sufficient justification for the expenditure of NRC resources to conduct a reciprocity inspection of a low-risk activity; in these cases, the decision should be documented. The basis for conducting such an inspection may include any of the criteria contained in IMC 2800¹ and, particularly, past performance information available from either the NRC or Agreement States concerning enforcement and/or inspection results. Announcing a low risk inspection may or may not be necessary. That decision is left to the discretion of the organization performing the inspection.